

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)

(19) World Intellectual Property Organization
International Bureau



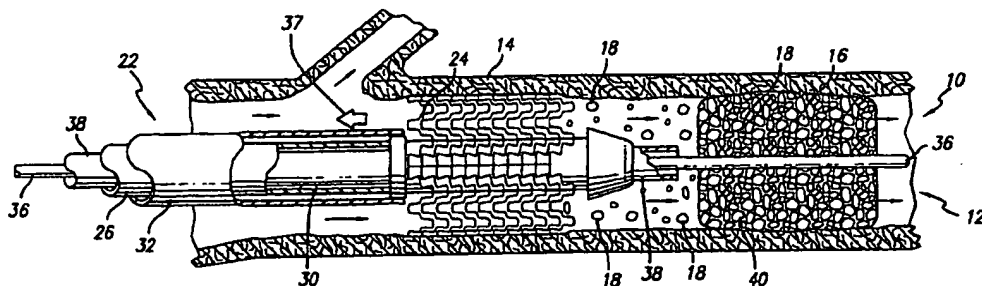
(43) International Publication Date
21 June 2001 (21.06.2001)

PCT

(10) International Publication Number
WO 01/43662 A1

- (51) International Patent Classification⁷: A61F 2/01
- (21) International Application Number: PCT/US00/33905
- (22) International Filing Date:
14 December 2000 (14.12.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/466,366 17 December 1999 (17.12.1999) US
- (71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95054-2087 (US).
- (72) Inventors: DUTTA, Debashis; 480 Oak Grove Drive, #307, Santa Clara, CA 95054 (US). HUTER, Benjamin, C.; 24375 Jackson Avenue, Apt. 1-307, Murrieta, CA 92562 (US). HUTER, Scott, J.; 43390 Corta Almeria, Temecula, CA 92592 (US). SIMPSON, John, A.; 7647 Primavera Way, Carlsbad, CA 92009 (US). STALKER, Kent, C., B.; 702 Pascali Court, San Marcos, CA 92069 (US).
- (74) Agents: NAGY, John, S. et al.; Fulwider Patton Lee & Utecht, LLP, Howard Hughes Center, Tenth Floor, 6060 Center Drive, Los Angeles, CA 90045 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEM FOR BLOCKING THE PASSAGE OF EMBOLI THROUGH A BODY VESSEL AND METHOD OF USE



(57) Abstract: An expandable filtering material expands within a body vessel (e.g. artery) when fluid flows through the vessel. Expandable pockets in the filtering material trap emboli released in the fluid. The filtering material is inserted into the vessel at a particular position distal to a lesion in the direction of the fluid flow. A protective sleeve covers the filtering material. An interventional device is disposed in the vessel at the lesion position to treat the lesion. The sleeve is removed from the expandable filtering material thereby expanding the filtering material within the vessel. The interventional device treats the lesion and opens up the vessel at the lesion position. The interventional device is thereafter removed. Retaining pockets in the expandable filtering material trap emboli released in the fluid of the body vessel. The sleeve is thereafter disposed over the filtering material to contract the filtering material after the pockets in the expandable filtering material have trapped the emboli. The contracted filtering material and the sleeve are removed from the vessel, with the emboli retained in the pockets. An expandable hydrogel which expands when subjected to a stimulus (e.g. temperature, pH, electrical field, solvent) and contracts when the stimulus is removed may be used for the filtering material.

WO 01/43662 A1

SYSTEM FOR BLOCKING THE PASSAGE OF EMBOLI THROUGH A BODY VESSEL AND METHOD OF USE

BACKGROUND OF THE INVENTION

This invention relates to a system for, and a method of, treating occluded vessels (e.g. an artery) and capturing friable emboli which may break away from the lesion in the vessel during an interventional procedure. The system and method of the present invention are especially useful when performing carotid interventional
5 procedures in order to prevent embolic debris from entering and occluding downstream blood vessels leading to the brain which, if blocked, may cause a stroke. However, the system and method of this invention can be adapted by a person of ordinary skill in the art for use in numerous other vascular interventional procedures.

In recent years, numerous procedures have been adapted for expanding
10 blood vessels (e.g. arteries) at the positions of lesions in the blood vessels so that blood can flow through the blood vessels without obstruction from the lesions. In the process of expanding such blood vessels at the positions of the lesions, emboli may become detached from the lesions and enter the bloodstream and subsequently migrate through the patient's vasculature to cut off or reduce the amount of oxygenated blood
15 supplied to sensitive organs such as the brain, which may induce trauma.

Procedures have also been adapted in recent years for preventing embolic debris from flowing through the vessels in the direction of the blood flow. For example, filters have been provided for trapping the emboli. When lesions develop in the carotid artery of a patient, the placement of a filter in the patient's vasculature can
20 somewhat reduce the movement of emboli to blood vessels leading to the patient's brain, thereby preventing strokes from occurring.

Such filters are usually delivered in a collapsed position through the patient's vasculature and are then expanded once in place in the patient's blood vessel to trap the emboli. After emboli have been trapped, the filter is collapsed and removed
25 (with the trapped emboli) from the vessel. Unfortunately, it is possible for some of the trapped emboli to escape from the filter during the time that the filter is being

collapsed and/or removed from the blood vessel. When an interventional procedure is being performed in a carotid artery, even a trace release of emboli can be damaging.

For these reasons, attempts to treat lesions in the carotid arteries have been somewhat limited due to the danger presented if all of the embolic debris is not collected during
5 the procedure.

Therefore, in light of the above, it would be desirable for a system and method which can be utilized to treat an occluded vessel and trap any emboli that may be formed during the vascular procedure. Such an apparatus and method must also prevent the emboli from escaping from the filter during the time that the filter is being
10 collapsed and/or removed from the blood vessel (e.g. the carotid arteries). Such a device or method should be easy and safe to deploy, and be easily removed from the vasculature with little or no adverse impact or immunological response to the patient.

SUMMARY OF THE INVENTION

The present invention is directed to a system for trapping and removing
15 emboli from a body vessel (e.g., an artery) which utilizes an expandable filtering material (e.g., an open-cell foam material) which expands within a vessel when fluid (e.g. blood) flows through the vessel. Retaining pockets formed in the expandable filtering material trap emboli which may be released in the fluid flow of the vessel. The expandable filtering material is inserted into the vessel at a particular position
20 distal to the lesion in the direction of the fluid flow. A protective sleeve covers the expandable filtering material as the filtering material is being deployed in the vessel. An interventional device, such as an expandable member (e.g., a balloon) and a stent, is disposed in the vessel to treat the lesion. The protective sleeve is removed from the expandable filtering material when the filter is to be deployed, thereby exposing the
25 filtering material to the fluid within the vessel which causes the filtering material to expand within the vessel. The interventional device can then be utilized to treat the lesion and expand the vessel at the lesion position.

The interventional device is thereafter collapsed and removed from the vessel. Emboli created during the interventional procedure are released into the fluid flow (e.g. bloodstream) and are trapped within the retaining pockets formed in the expandable filtering material. The protective sleeve is then disposed over the
5 expandable filtering material to contract the material for removal from the vessel. The filtering material and the sleeve can be removed from the vessel, with the trapped emboli retained in the pockets of the filtering material.

In another embodiment, an expandable hydrogel is affixed to the end of a catheter and used in a similar manner to trap and retain emboli released into the
10 vessel. The hydrogel material will swell or expand when subjected to a external stimulus (e.g., temperature, pH, electrical fields, magnetic fields, solvent, ionic strength, pressure, stress, light intensity and chemicals such as glucose) and will contract or shrink when the stimulus is removed. The hydrogels may be used in place of the expandable filtering material to capture embolic debris released in the vessel.

15 These and other advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

20

FIG. 1 is a elevational view, partially in section, of a first preferred embodiment of a system for expanding a vessel at a position of a lesion and capturing emboli released into the vessel as a result of the performance of an interventional procedure.

25

FIG. 2 is an enlarged fragmentary elevational view, primarily in section, of the preferred embodiment of FIG. 1 showing the expandable filtering material expanded within the vessel at a position distal to the lesion.

FIG. 3 is an enlarged fragmentary elevational view, primarily in section, showing the expandable filtering material in its expanded condition and a self-expanding stent and stent delivery catheter disposed at the position of the lesion with the stent expanded against the wall of the vessel.

5 FIG. 4 is an enlarged fragmentary elevational view, primarily in section, showing the expandable filtering material in a contracted condition as the protective sleeve covers and compresses the filtering material.

FIG. 5 is an enlarged fragmentary elevational view, partially in section, showing the protective sleeve and the filtering material being withdrawn from the
10 vessel.

FIG. 6 is an elevational view, primarily in section, of another preferred embodiment of the invention showing a porous hydrogel material affixed to the distal end of a catheter and retained in a protective sleeve.

FIG. 7 is an elevational view, primarily in section, of the embodiment of
15 FIG. 6 showing the porous hydrogel material in an expanded or swollen condition after the protective sleeve has been removed and a stimulus has been applied to the hydrogel material.

FIG. 8 is an elevational view, primarily in section, of another preferred embodiment of the invention showing a porous hydrogel material affixed to the distal
20 end of a catheter and retained in a protective sleeve.

FIG. 9 is an elevational view, primarily in section, of the embodiment of FIG. 8 showing the porous hydrogel material in an expanded or swollen condition after

the protective sleeve has been removed and a stimulus has been applied to the hydrogel material.

FIG. 10 is an elevational view, primarily in section, of another preferred embodiment of the invention showing a porous hydrogel material affixed to the distal
5 end of a catheter and retained in a protective sleeve; and

FIG. 11 is an elevational view, primarily in section, of the embodiment of FIG. 10 showing the porous hydrogel material in an expanded or swollen condition after the protective sleeve has been removed and a stimulus has been applied to the hydrogel material.

10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A first preferred embodiment of a system, generally indicated at 10, is shown in FIGS. 1 - 5 of the drawings. The system 10 includes a catheter, generally indicated at 12, which is constructed to extend through a vessel 14, such as a patient's artery, and has an expandable filtering material 16 affixed to its distal end. The system
15 10 is adapted to be disposed in the vessel 14 (e.g., artery) to pass the fluid (e.g., blood) in the vessel and to block emboli 18 which may be released into the bloodstream. The emboli 18 are produced when the blood vessel 14 is treated at the position of a lesion 20 during an intervention procedure such as, a balloon angioplasty procedure, a stenting procedure, an atherectomy procedure and the like. The present invention is
20 designed to collect and remove such embolic debris from the artery to prevent the blockage of the smaller vessels downstream from the area of treatment. The system 10 is especially adapted to prevent blockage of small blood vessels leading to the brain which, if blocked, can cause the patient to suffer a stroke.

An interventional device, such as a stent delivery catheter 22 and a self-
25 expanding stent 24, can be utilized to treat the lesion 20 and open up the artery 14 to

increase blood flow therethrough. This stent delivery catheter 22 and the stent 24 may be constructed in a manner well known in the art. The delivery catheter 22 and the stent 24 may be disposed at the position of the lesion 20 as shown schematically in FIG. 1. The delivery catheter 22 includes an inner tubular member 26 onto which the
5 compressed or collapsed stent is mounted. This inner tubular member 26 includes an inner lumen 30 which allows the member 26 to be disposed over the catheter 12 in a co-axial arrangement. This allows the stent delivery catheter 22 to be delivered to the area of treatment using over-the-wire techniques. An outer restraining sheath 32 extends over the inner tubular member 26 in a co-axial arrangement and is used to
10 restrain the collapsed stent until it is ready to be deployed. Both the outer restraining sheath 32 and inner tubular member 26 have proximal ends (not shown) which extend outside of the patient. In use, the physician moves the proximal ends to retract the restraining sheath the necessary length to deploy the stent 24. Once the stent is positioned across the lesion 20, the restraining sheath 32 can be retracted to expose the
15 stent 24 to allow it to expand against the wall 34 of the vessel 14. The opening in the vessel 14 is maintained by the stent 24 even after the delivery catheter 22 is withdrawn from the vessel.

The catheter 12 includes an inner member 36 to which the expandable filtering material 16 is affixed. A restraining or protective sleeve 38 also forms part of
20 the catheter 12 and is used to maintain the filtering material 16 in its compressed position, free from any body fluids which would tend to cause the filtering material to expand. This restraining sleeve 38 is also used, as will be described below, to retrieve the expanded filtering material after emboli have been trapped in retaining pockets or cavities 40 formed on the filtering material 16. The filtering material has properties
25 of expanding when subjected to fluid, such as blood. For example, the filtering material 16 may be formed from a flexible, open-cell foam material exhibiting sponge-like properties. Suitable materials include foamed material made from suitable elastomeric polymer, or a combination thereof, such as latex, silicone, neoprene or natural rubber. Additionally, cellulose polyester, or any plastic which can be formed

or blown into a sponge-like material could be used. This would include thermoplastics as well as thermoset plastics. The filtering material has properties of fully expanding within the vessel 14 while allowing fluids to flow therethrough. Emboli, however, will be trapped in retaining pockets 40 formed in the material. These pockets 40 retain the emboli even as the filtering material 16 has being contracted or collapsed and removed from the patient's vasculature.

When it is desired to expand the vessel 14 at the position of the lesion 20 in the vessel, the protective sleeve 38 is initially retracted to expose the filtering material 16 to the blood flow. This is indicated by a hollow arrow 33 in FIG. 2. The filtering material 16 expands within the vessel 14 as a result of the flow of the fluid (e.g., blood) through the material. This is shown in FIG. 2. The direction of the fluid flow in the vessel 14 is indicated by solid black arrows 35 in the drawings.

The stent delivery catheter 22 can then be used to expand the stent 24 against the vessel 14 at the position of the lesion 20. This is shown in FIG. 3. This causes the vessel 14 to expand at the position of the lesion 20 so as to open the vessel. This is shown schematically in FIG. 3. Fluid and any emboli 18 from the lesion 20 then flow through the vessel 14 into the filtering material 16. Fluid is allowed to pass through the filtering material 16 while emboli 18 are trapped in the retaining pockets 40. This also is indicated schematically in FIG. 3.

When all of the emboli have been trapped in the pockets 40, the delivery catheter 22 is removed from the vessel 14. This is indicated by a hollow arrow 37 in FIG. 3. The stent 24 remains in the expanded vessel 14 at the position of the lesion 20.

As shown in FIG. 4, the protective sleeve 38 is then disposed over the filtering material 16 to contract or collapse the material. During the contraction or collapse of the filtering material, the trapped emboli 18 are retained in the pockets 40, particularly since the pockets 40 also are being contracted or collapsed in accordance with the contraction or collapsing of the filtering material. The sleeve 38 and filtering

material 16 are then removed from the vessel 14 as indicated by a hollow arrow 41 in FIG. 5.

The system 10 may be used in conjunction with current compatible devices. For example, the system 10 may be used in conjunction with balloon
5 dilatation catheters, stent delivery systems, ultrasonic and laser angioplasty devices and atherectomy catheters and other medical devices. The system 10 will preferably be used during vascular intervention, in particular, carotid artery angioplasty and stenting (i.e. pre-dilation, stenting, post-dilation), however, it can also be used in any procedures in which the potential release of emboli debris poses a problem.

10 FIGS. 6 through 11 show other preferred embodiments of the invention. In these preferred embodiments, a porous hydrogel material generally indicated at 50 may be used in place of the filtering material 16 to pass fluid through the vessel 14 and block the passage of emboli 18. The porous hydrogels 50 have properties of changing
15 their volume rather abruptly from a time standpoint upon small changes in such parameters or stimuli as temperature, pH, electrical fields, magnetic fields, solvent, ionic strength, pressure, stress, light intensity and chemicals such as glucose.

For example, porous hydrogels have been made to expand (or swell) and compress (or shrink) within tens of seconds by subjecting the porous hydrogel to changes in the different parameters specified above. When swelled or expanded, the
20 hydrogels have an open-celled microporous structure. The size of the pores or openings or cavities 52 in the hydrogel can range from approximately one (1) micron to approximately hundreds of microns. Satisfactory hydrogels for use in this application have been disclosed in the published literature. This published literature includes the following:

25 (1) An article entitled "SUPERPOROUS HYDROGELS: FAST RESPONSE HYDROGEL SYSTEMS" and written by Jun Chen, Haesan Park and Kinam Park and published on pages 236 and 237 of Volume 79 in 1998 in The American Chemical Society PMSE Abstracts;

(2) An article written by Ron Dagani and entitled "INTELLIGENT GELS" and published in 1997 on pages 26 - 37 of Volume 75 of Chemical Engineering News; and

(3) An article written by Peppas et al. and published in 1991 on page 715 (and
5 following pages) in Volume 46 of Cem. Eng. Sci.

Examples of "smart" (responsive to changes) hydrogels include:

(1) pH sensitive hydrogels such as poly (acrylamide co-acrylic acid); poly (NIPAM-co-AM), Such pH sensitive hydrogels are disclosed in references 1 and 3 specified in the previous paragraph;

10 (2) Temperature responsive hydrogels such as poly (acrylic acid) - g - PEO - PPO - PEO. Such temperature responsive hydrogels are disclosed in reference 2.

The porous hydrogels 50 can be applied in their contracted or shrunken state as low profile coatings on the distal tip of catheters 54. This is indicated
15 schematically in FIGS. 6, 8 and 10. Alternatively, the porous hydrogels 50 can be applied in their shrunken state on the distal tips of guidewires/hypotubes in an embolic protection device. The porous hydrogel 50 may be covered in its shrunken state by a protective sleeve 56. The catheter 54 or, alternatively, the guidewire is then inserted into the vessel 14 and is passed through the vessel to a position past the lesion in the
20 direction of the fluid flow. The sleeve 56 may be removed as indicated by a hollow arrow 57. The porous hydrogel 50 is then expanded or swelled within the vessel by providing the hydrogel with a change in the appropriate parameter or stimuli specified above. This expansion or swelling can be provided to any desired value such as approximately five (5) to approximately one hundred (100) times the shrunken value.

25 When the porous hydrogel 50 is swelled or expanded, it presses against the wall of the vessel. It also causes the pores or pockets or cavities 52 to expand throughout the expanded or swollen structure of the hydrogel 50. In this way, when the interventional device is used to treat the lesion, any emboli separated from the lesion become entrapped in the expanded pores, pockets or cavities 52 and are thereby

prevented from passing through the hydrogel. However, the fluid (e.g. blood) in the vessel is able to pass through the porous hydrogel 50.

After the interventional procedure is completed, the interventional device is withdrawn from the vessel. The porous hydrogel 50 is then contracted or shrunk
5 from their expanded positions shown in FIGS. 7, 9 and 11 to the positions respectively shown in FIGS. 6, 8 and 10. This is accomplished by withdrawing the parameters or stimuli previously providing the expansion or swelling of the porous hydrogel.

The pores or cavities 52 shrink as the porous hydrogel 50 shrinks. This
10 causes the retention of the emboli within the pores or cavities 50 to become enhanced, thereby allowing the hydrogel to block the passage of the emboli past the hydrogel and remain entrapped in the pores 52. When the porous hydrogel 50 becomes contracted or shrunken, the porous hydrogel is withdrawn from the body vessel.

FIGS. 6 and 7 shown a preferred embodiment for producing changes in
15 parameters or stimuli in the porous hydrogel element 50, the contracted or shrunken hydrogel element being shown in FIG. 6 and the expanded or swollen hydrogel element being shown in FIG. 7. In the preferred embodiment shown in FIGS. 6 and 7, a hollow tube 58 is provided for introducing changes in a parameter or stimulus to the porous hydrogel element 50. For example, this change in the parameter or stimulus
20 may relate to changes in pH, solvent, ionic strength, pressure or chemicals such as glucose.

FIGS. 8 and 9 show another preferred embodiment for producing changes in parameters or stimuli in the porous hydrogel element 50, the contracted or shrunken hydrogel element being shown in FIG. 8 and the expanded or swollen
25 hydrogel element being shown in FIG. 9. In this preferred embodiment, an electrical wire 60 may be provided for introducing the changes in the parameter or stimulus to the porous hydrogel element 50. As shown in FIGS. 8 and 9, the wire 60 may be wound on the catheter 54. For example, the changes in parameters or stimuli may constitute changes in temperature, electrical fields, magnetic fields and light intensity.

FIGS. 10 and 11 show still another preferred embodiment of the invention for producing changes in parameters or stimuli in the porous hydrogel. In this embodiment, the shrunken hydrogel element 50 is shown in FIG. 10 and the expanded or swollen hydrogel element is shown in FIG. 11. In this preferred
5 embodiment, a solid tube 62 extends into the porous hydrogel 50 for introducing changes in a parameter or stimulus into the hydrogel. For example, this change in the parameter or stimulus may relate to changes in temperature, pressure, stress, or light intensity.

It should be appreciated that the embodiments shown in FIGS. 6 through
10 11 represent only a few different ways in which changes in parameters or stimuli can be provided to the porous hydrogel 50. It will be apparent to persons of ordinary skill in the art how the changes in parameters or stimuli can be introduced to the porous hydrogel 50 in other ways than those shown in FIGS. 6 through 11 and described above.

15 The different preferred embodiments of this invention have several common advantages. They employ, at positions after the lesion, in the direction of the fluid flow, filtering material which expand or swell to trap emboli and which contract or shrink, after trapping the emboli, to retain the emboli while the filter is being withdrawn from the vessel 14. The preferred embodiments shown in FIGS. 6 - 11
20 have an additional advantage in that they do not have to be covered by a sheath or sleeve, as the filtering material 16 of the embodiment shown in FIGS. 1-5, in order to contract or shrink, thereby simplifying the process of withdrawing the filter from the vessel while maintaining all of the emboli within the filter.

Although this invention has been disclosed and illustrated with reference
25 to particular embodiments, the principles involved are susceptible for use in numerous other embodiments which will be apparent to persons of ordinary skill in the art. The invention is, therefore, to be limited only as indicated by the scope of the appended claims.

WHAT IS CLAIMED:

1. A device for passing a fluid through a vessel while blocking the passage of emboli through the vessel, comprising:

- a filtering material having properties of being expanded within the vessel
5 when subjected to an external stimulus and having properties of passing fluid therethrough while blocking the passage of emboli contained in the fluid, the filtering material being normally in a contracted condition for positioning within the vessel.

2. The device of claim 1, wherein:

the filtering material constitutes an open-cell foam material exhibiting sponge-like properties and the filtering material is expandable within the vessel when subjected to a fluid in the vessel.

3. The device of claim 1, wherein:

- the filtering material constitutes a porous hydrogel and is expandable within the vessel when subjected to a stimulus selected from a group consisting of temperature, pH, electrical field, magnetic field, ionic field, pressure, stress, light
5 intensity, solvent, and chemicals.

4. The device of claim 2, further including:

a sleeve which can be placed over the filtering material to contract the filtering material after trapping emboli.

5. The device of claim 3, wherein:

the filtering material has properties of being contracted when the stimulus is removed from the filtering material.

6. A system for treating a lesion in a body vessel and allowing fluid to pass through the vessel while blocking the passage of emboli released in the fluid, comprising:

- 5 a filtering material disposable in the vessel at a position past the lesion which is contractable and expandable, the filtering material being contracted during positioning in the vessel and being expandable when subjected to an external stimulus, the filtering material having properties when expanded for passing fluid therethrough while blocking the passage of the emboli; and
- an interventional device for treating the lesion in the vessel.

7. The system of claim 6, wherein:

the filtering material constitutes an open-cell foam material exhibiting sponge-like properties expandable when the filtering material is subjected to a fluid in the vessel and having a plurality of pockets for retaining emboli.

8. The system of claim 6, wherein:

- the filtering material constitutes a porous hydrogel expandable when the filtering material is subjected to a stimulus selected from a group consisting of temperature, pH, electrical field, magnetic field, ionic field, pressure, stress, light
- 5 intensity, solvent, and chemicals.

9. The system of claim 7, further including:

a sleeve which can be placed over the filtering material to contract the filtering material after trapping emboli.

10. The system of claim 8, wherein:

the hydrogel has properties of contracting when the stimulus is removed.

11. A system for passing a fluid through a body vessel while blocking the passage of emboli in the vessel, comprising:

a filtering member made from an open-cell foam material exhibiting sponge-like properties and having properties of expanding when subjected to a fluid,

5 the filtering member being constructed to retain emboli released in the fluid of the vessel; and

a catheter attached to filtering member for inserting the filtering member into the vessel at a particular position.

12. The system of claim 11, wherein:

the filtering member is provided with contractible properties and wherein the filtering member is provided with hollow pockets to trap the emboli when the filtering member is expanded within the vessel and to retain the emboli in the
5 hollow pockets when the filtering member is thereafter contracted.

13. The system of claim 11, further including:

a sleeve which covers the filtering member in a contracted condition until the filtering member is positioned in the vessel to expand within the vessel and to block the flow of the emboli through the filtering member.

14. The system of claim 12, further including:

a sleeve which covers the filtering member in a contracted condition until the filtering member is positioned in the vessel to expand within the vessel and block the flow of the emboli through the filtering member and the sleeve is disposed
5 on the filtering member to contract the filtering member after the filtering member has blocked the flow of the emboli through the filtering member.

15. A system for passing a fluid through a vessel while blocking the passage of emboli in the vessel, comprising:

a filtering member made from a filtering material having properties of expanding when subjected to a fluid and having properties of passing fluid while blocking the passage of emboli when expanded, the filtering member being normally disposed in a contracted condition for positioning the filtering member in the vessel and having properties of being expanded after the disposition of the filtering member in the vessel.

16. The system of claim 15, including:

a sleeve removably disposed on the filtering member for retaining the filtering member in the contracted condition, there being a plurality of pockets in the filtering member with dimensions for trapping the emboli thereby preventing the emboli from passing through the filtering member.

17. The system of claim 16, wherein:

the sleeve is constructed to be disposed on the filtering member after the trapping of emboli by the filtering member to facilitate the removal of the filtering member from the vessel and to retain the emboli in the filtering member during such removal.

18. The system of claim 17, wherein:

the filtering member is made from an open-cell foam material exhibiting sponge-like properties.

19. The system of claim 16, wherein:

the filtering member constitutes a porous hydrogel.

20. A method of passing fluid in a vessel while blocking the passage of emboli from a lesion in the vessel, including the steps of:

providing on a catheter a filtering material having properties of expanding within the vessel when subjected to a fluid and having properties of passing
5 the fluid while blocking the passage of emboli when expanded,

providing a sleeve on the filtering material when the filtering material is contracted,

disposing the filtering material, the catheter and the sleeve in the vessel,
and

10 removing the sleeve from the filtering material to expose the filtering material to fluid in the vessel, thereby providing for an expansion of the filtering material within the vessel and for the retention of the emboli by the filtering material.

21. A method as set forth in claim 20, wherein:

pockets are provided in the filtering material to trap the emboli flowing through the vessel and to retain the emboli in the pockets when the filtering material is removed from the vessel.

22. A method as set forth in claim 21, wherein:

the sleeve is thereafter disposed on the filtering material to contract the filtering material after the pockets of the filtering material have trapped the emboli and the sleeve, the filtering material and the catheter are removed from the vessel, after the
5 filtering material has been covered by the sleeve, with the emboli remaining in the pockets of the filtering material.

23. A method as set forth in claim 22, wherein:

the filtering material constitutes an open-cell foam material having sponge-like properties.

24. A method as set forth in claim 21, wherein:
the filtering material is a porous hydrogel.

25. A system for treating a lesion in a body vessel and passing a fluid through a vessel while blocking the passage of emboli in the fluid, comprising:
a filtering material disposable in the vessel at a position past the lesion in the direction of fluid flow, the filtering material being contractible and expandable,
5 the filtering material being normally contracted and having properties of expanding within the vessel when exposed to a fluid in the vessel, the filtering material having properties when expanded for passing the fluid in the vessel while blocking the passage of the emboli in the vessel; and
an interventional device for treating the lesion.

26. The system of claim 25, wherein:
pockets are disposed in the expandable material to trap the emboli flowing in the vessel.

27. The system of claim 26, wherein:
a sleeve is disposed on the expandable filtering material in the contracted condition to provide for the movement of the expandable filtering material and the sleeve through the vessel to a position distal to the lesion in the direction of the fluid
5 flow; and
the sleeve is removable from the expandable filtering material to provide for the expansion of the expandable filtering material and to provide for the trapping of the emboli in the pockets of the expandable member.

28. The system of claim 27, wherein:
the expandable filtering material constitutes an open-cell foam material exhibiting sponge-like properties.

29. The system of claim 26, wherein:

the expandable filtering material constitutes a porous hydrogel expandable when the filtering material is subjected to a stimulus selected from a group consisting of temperature, pH, electrical field, magnetic field, ionic field, pressure, stress, light, solvent and chemicals.

30. A method for treating a lesion in a body vessel and passing fluid in the vessel while capturing emboli created during the treatment procedure in the vessel, including the steps of:

providing an interventional device for treating the lesion in the vessel,
providing an expandable filtering material having properties of expanding within the vessel and having properties of trapping emboli to prevent the emboli from flowing in the vessel through the expandable filtering material,
the expandable filtering material being contractible,
disposing the interventional device at the position of the lesion in the vessel and the expandable filtering material in a contracted condition to a position distal to the lesion in the direction of the fluid flow,
expanding the expandable member within the vessel,
treating the lesion with the interventional device,
removing the interventional device from the vessel, and
providing for the contraction of the expandable filtering material and the removal of the expandable filtering material from the vessel.

31. A method as set forth in claim 30, including the step of:

providing the expandable filtering material with pockets having characteristics for receiving the emboli with the expandable filtering material expanded and for retaining the emboli with the expandable filtering material contracted.

32. A method as set forth in claim 30, wherein:

the expandable filtering material is made from an open-cell foam material exhibiting sponge-like properties.

33. A method as set forth in claim 31, wherein:

the expandable filtering material is disposed in a sleeve in the contracted relationship during the movement of the expandable filtering material in the vessel to the position distal to the lesion in the direction of the fluid flow,

5 the sleeve is removed from the expandable filtering material upon the movement of the expandable filtering material to the position past the lesion in the direction of the fluid flow, thereby to provide for the expansion of the expandable filtering material against the vessel, and

the sleeve is disposed on the expandable filtering material after the
10 trapping of the emboli in the expandable filtering material to provide for the contraction of the expandable filtering material.

34. A method as set forth in claim 30, including the steps of:

providing the expandable filtering material with pockets having characteristics for receiving and retaining the emboli with the expandable filtering material expanded and wherein

5 the expandable filtering material constitutes an open-cell foam exhibiting sponge-like properties and wherein:

the expandable filtering material is disposed in a sleeve in the contracted relationship during the movement of the expandable filtering material in the vessel to the position past the lesion in the direction of the fluid flow,

10 the sleeve is removed from the expandable filtering material upon the movement of the expandable filtering material to the position past the lesion in the direction of the fluid flow, thereby to provide for the expansion of the expandable filtering material against the vessel,

the sleeve is disposed on the expandable filtering material after the
15 trapping of the emboli in the expandable filtering material to provide for the
contraction of the expandable filtering material, and

the expandable filtering material is constructed in the inflatable
relationship to pass the fluid and to trap the emboli.

35. A method as set forth in claim 30, wherein:

the expandable filtering material constitutes a porous hydrogel having
properties of expanding when subjected to a stimulus.

36. A method as set forth in claim 35, wherein:

the porous hydrogel has properties of contracting when the stimulus is
removed.

37. A method as set forth in claim 30, wherein:

the expandable filtering material constitutes a porous hydrogel having
properties of expanding when subjected to a stimulus,

the stimulus is selected from a group consisting of temperature, pH,
5 electrical field, magnetic field, ionic field, pressure, stress, light intensity, solvent and
chemicals, and

the hydrogel has properties of contracting when the stimulus is removed.

38. A method for treating a lesion in a body vessel and for passing
fluid in a vessel while blocking passage of emboli created from the treatment of the
lesion, including the steps of:

providing a filtering material having expandable and contractible
5 properties, the filtering material being normally contracted and having properties of
expanding when subjected to a stimulus external to the filtering material,

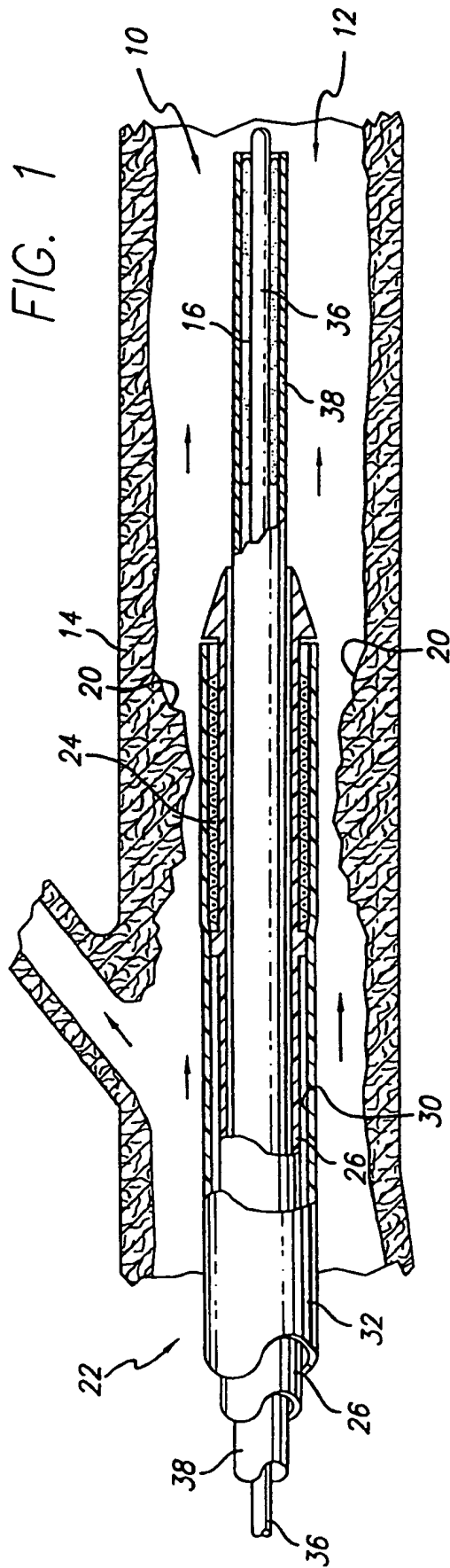
disposing the filtering material in the vessel at a position past the lesion
in the direction of the fluid flow,
subjecting the filtering material to the stimulus to provide an expansion
10 of the filtering material against the vessel, and
compressing the lesion to expand the opening in the vessel.

39. In a method as set forth in claim 38, wherein:
the filtering material constitutes a sponge having properties of expanding
when subjected to a fluid in the vessel.

40. In a method as set forth in claim 38, wherein:
the filtering material constitutes a porous hydrogel having properties of
expanding when subjected to a change in the stimulus and of contracting when the
change in the stimulus is removed.

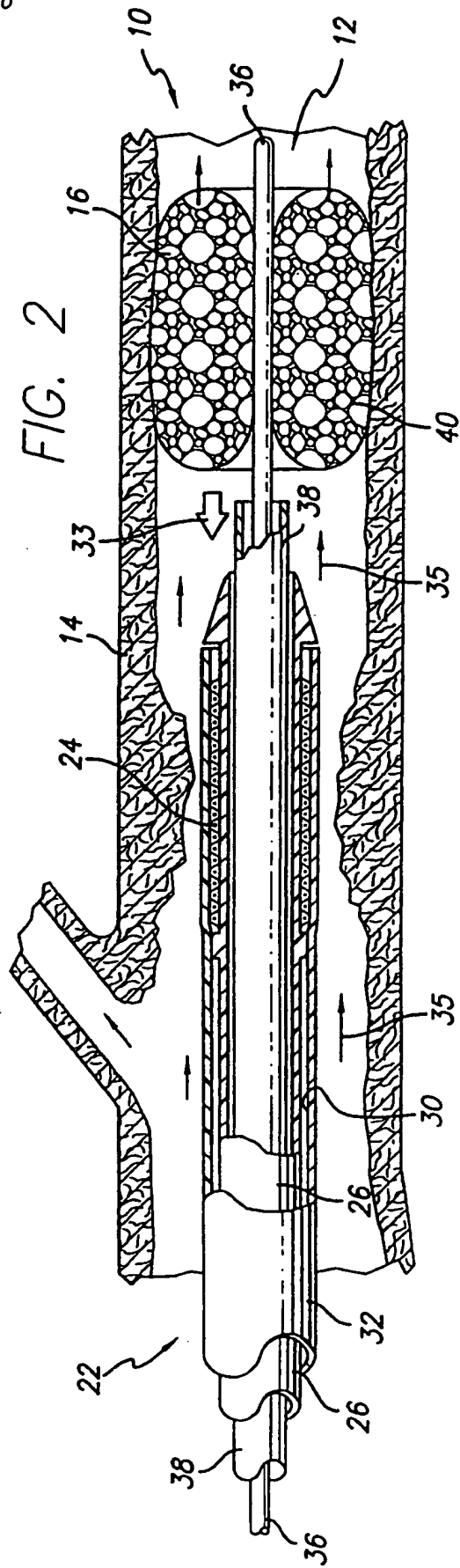
41. In a method as set forth in claim 40, wherein;
the stimulus is selected from a group consisting of temperature, pH,
electrical field, solvent, magnetic field, ionic field, pressure, stress, light intensity and
chemicals.

FIG. 1



1/6

FIG. 2



3/6

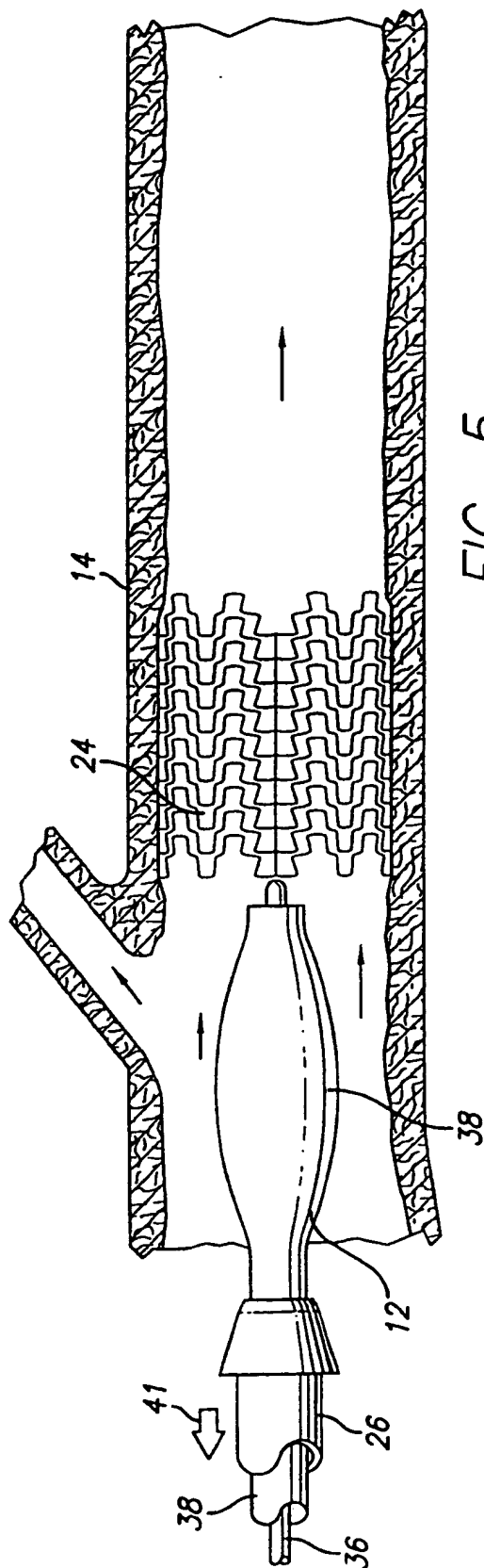
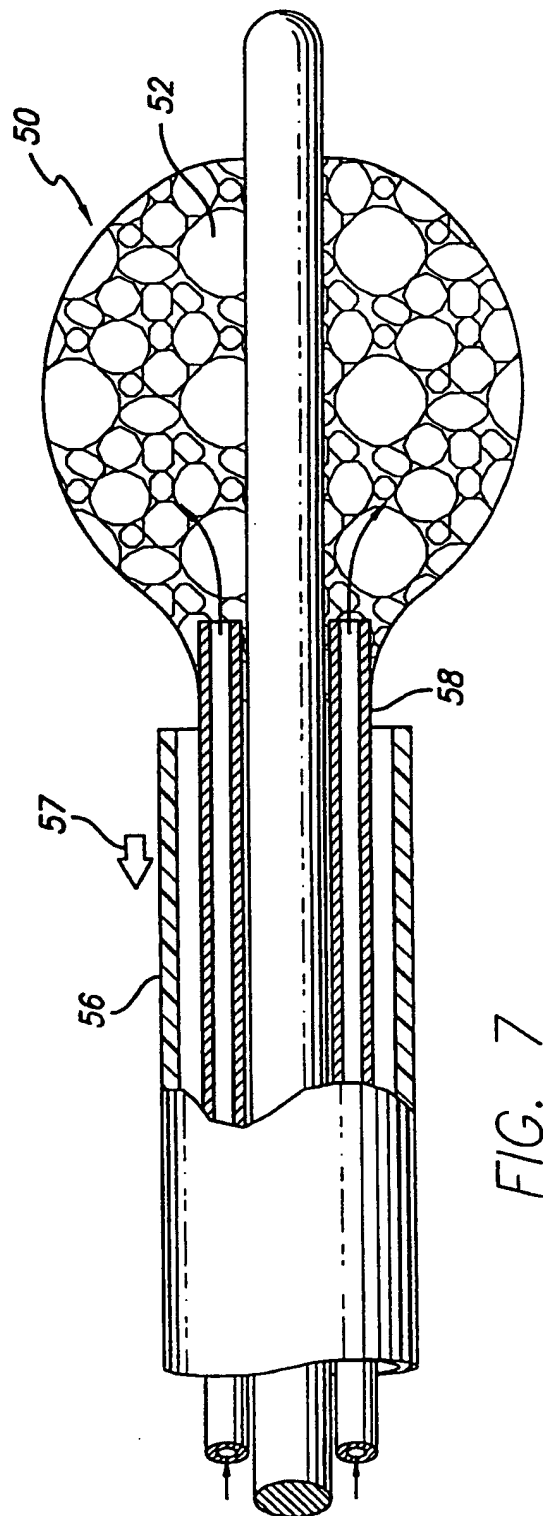
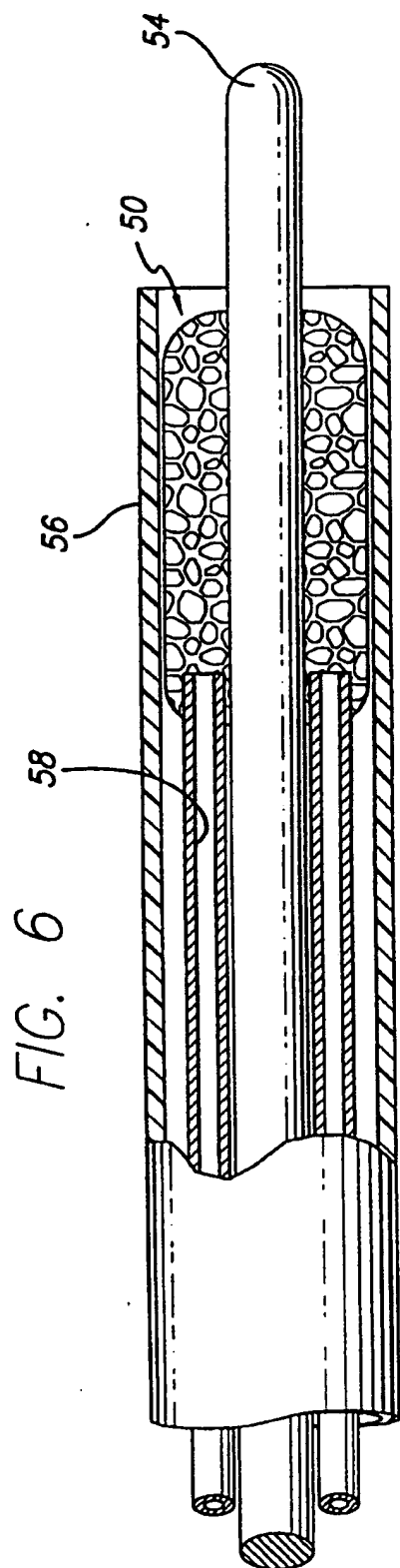
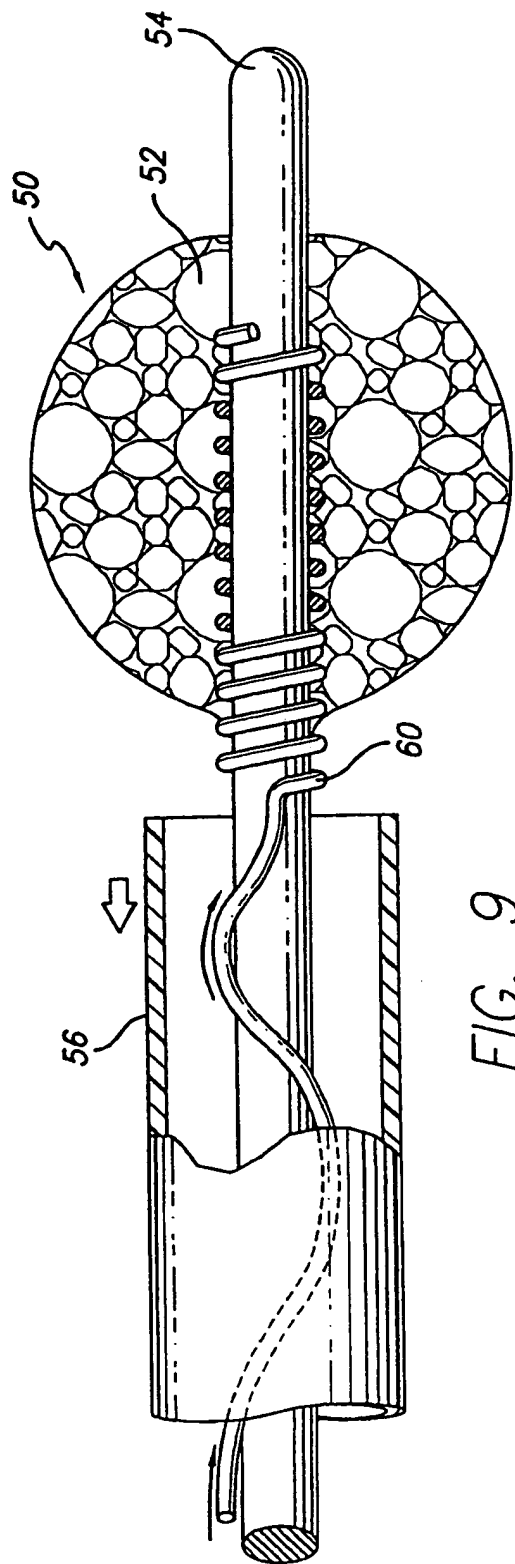
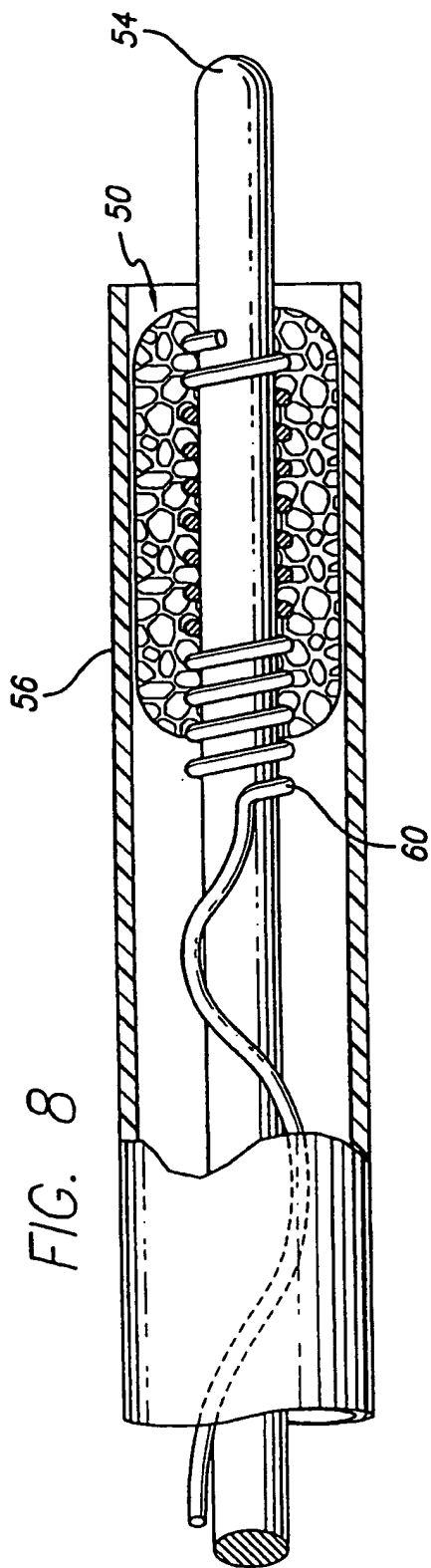
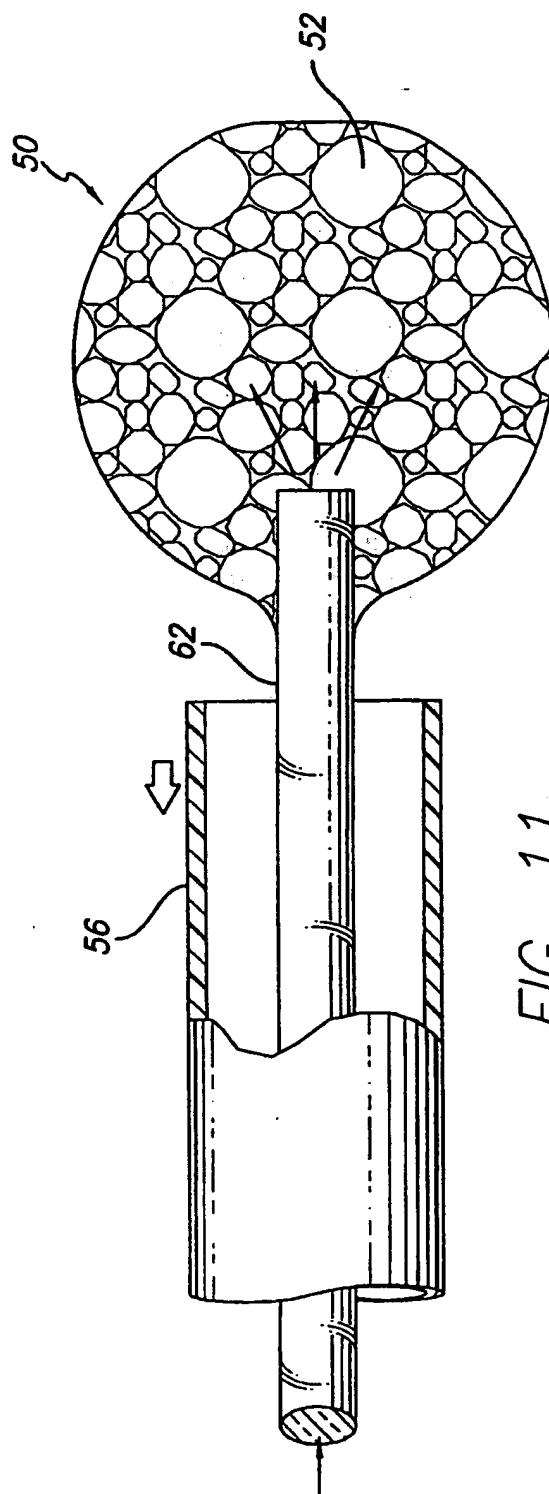
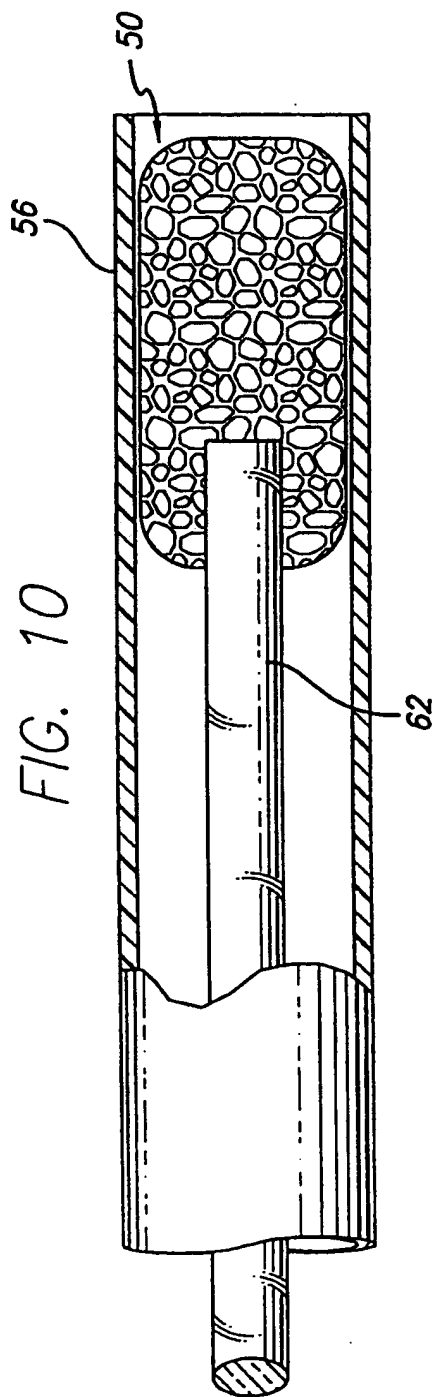


FIG. 5







INTERNATIONAL SEARCH REPORT

In ational Application No

PCT/US 00/33905

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 23976 A (SALVIAC LIMITED) 20 May 1999 (1999-05-20) page 16, line 14 -page 18, line 30; figures 1-10 -----	1,6,11, 15,25

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

7 March 2001

Date of mailing of the international search report

14/03/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Smith, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/33905

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9923976 A	20-05-1999	AU 9758398 A	31-05-1999
		BR 9813935 A	19-09-2000
		DE 19882777 T	26-10-2000
		DE 29880158 U	30-11-2000
		EP 1028670 A	23-08-2000
		GB 2345253 A	05-07-2000
		IE 81060 B	12-01-2000
		NO 20002303 A	04-05-2000
		PL 340258 A	29-01-2001
